16p.
TW3980

Robert A. Zeman, Esquire (State Bar No. 149095)
LAW OFFICES OF ROBERT A. ZEMAN
5142 Hollister Avenue, No. 195
Santa Barbara, CA 93111
Telephone: 805-682-0360
E-Mail: rzemanlaw@gmail.com

Alan C. Milstein, Esquire (*Pro Hac Vice* Forthcoming)
SHERMAN, SILVERSTEIN, KOHL,
ROSE & PODOLSKY, P.A.
A Professional Corporation
308 Harper Drive, Suite 200
Moorestown, NJ 08057
Telephone: 856-662-0700
Facsimile: 856-488-4744
E-Mail: amilstein@shermansilverstein.com

Attorneys for Plaintiff ANITA LAUX

SUPERIOR COURT OF THE STATE OF CALIFORNIA
COUNTY OF VENTURA

ANITA LAUX,

Plaintiff,

vs.

MENTOR WORLDWIDE, LLC; MENTOR CORPORATION; ETHICON, INC.; JOHNSON & JOHNSON; and JOHN DOE DEFENDANTS #1-10,

Defendants.

CASE NO.

COMPLAINT FOR DAMAGES

JURY TRIAL DEMANDED

Plaintiff Anita Laux, by and through her counsel Alan C. Milstein of Sherman, Silverstein, Kohl, Rose & Podolsky, P.A., and Robert A. Zeman, by way of Complaint against Mentor Worldwide, LLC; Mentor Corporation; Ethicon, Inc.; Johnson & Johnson; and John Doe Defendants #1-10, hereby says, states, and avers as follows:

PARTIES

1. Plaintiff Anita Laux is an individual who resides in Thousand Oaks, Ventura County, California. Her mailing address is P.O. Box 7212, Westlake Village, CA 91359.

2. Defendant Mentor Worldwide, LLC is a limited liability company organized and existing under the laws of the State of Delaware, with a principal place of business at 33 Technology Drive, Irvine, CA 92618.

3. Defendant Mentor Corporation is or was a corporation organized and existing under the laws of the State of Minnesota, with a principal place of business at 33 Technology Drive, Irvine, CA 92618.

4. Defendant Ethicon, Inc. is a corporation organized and existing under the laws of the State of New Jersey, with a principal place of business at One Johnson & Johnson Plaza, New Brunswick, NJ 08933.

5. On information and belief, Ethicon, Inc. is Mentor Worldwide LLC's parent company and owns 100% of the membership interests of Mentor Worldwide LLC.

6. On information and belief, Ethicon, Inc. is in turn a wholly owned subsidiary of Defendant Johnson & Johnson, a publicly traded corporation organized and existing under the laws of the State of New Jersey, with a principal place of business at One Johnson & Johnson Plaza, New Brunswick, NJ 08933.

7. In or around the year 2009, Mentor Corporation merged into, and/or became, Mentor Worldwide, LLC; and at or around that time Mentor Worldwide, LLC, Ethicon, Inc., Johnson & Johnson, and/or John Does #1-10 expressly and/or impliedly succeeded to the assets, liabilities, and obligations of Mentor Corporation, including but not limited to the obligation to answer in damages for the conduct alleged herein.

8. John Doe Defendants #1-10 are individuals and/or business entities responsible in whole or in part for the acts and omissions set forth herein, whose identities are presently unknown to the Plaintiff.

VENUE AND PERSONAL JURISDICTION

9. Venue is proper in Ventura County because, among other things, the Plaintiff is a resident of Ventura County, the injury occurred and had effect within Ventura County, and Defendants Mentor Worldwide, LLC and Mentor Corporation regularly do business within said county. *See* California Code of Civil Procedure § 395.

10. This Court has personal jurisdiction over Mentor Worldwide, LLC and Mentor Corporation, as said Defendants are residents of the State of California, and said Defendants otherwise have sufficient contacts with the State of California.

11. This Court has personal jurisdiction over Ethicon, Inc., and Johnson & Johnson, as said Defendants have sufficient minimum contacts with the State of California, and systematically and continuously transact business within the State of California, such that the exercise of personal jurisdiction over those Defendants does not offend traditional notions of fair play and substantial justice.

FACTS COMMON TO ALL COUNTS

12. On December 30, 2005, Ms. Laux underwent surgery at the hands of Juris Bunkis, M.D., who placed saline-filled inflatable breast implants manufactured by Defendant Mentor Corporation, Defendant Mentor Worldwide, LLC, and/or John Doe Defendants #1-10 ("Mentor Saline Breast Implants") into Ms. Laux's body.

13. Unbeknownst to Ms. Laux at the time, the Mentor Saline Breast Implants suffered from manufacturing defects.

14. Without limiting the generality of the foregoing, unbeknownst to Ms. Laux at the time,

a. The Mentor Saline Breast Implants suffered from a manufacturing defect whereby the shells, valves, and valve orifices and caps, among other

components, were not manufactured according to Mentor's own design and specifications;

b. The Mentor Saline Breast Implants suffered from a manufacturing defect because the shells, valves, and valve orifices and caps, among other components, were not manufactured in accordance with the FDA's Quality System Regulations and Current Good Manufacturing Practices, 21 C.F.R. § 820.1, *et seq.*, which among other things "require each manufacturer to put in place processes to test products for compliance with product specifications, to check and document compliance with product specifications before products are accepted for sale and use, and to identify and control nonconforming products," thereby rendering the device "adulterated." *See, e.g., Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010); and

c. The Mentor Saline Breast Implants suffered from a manufacturing defect because the shells, valves, and valve orifices and caps, among other components, were not manufactured in accordance with 21 U.S.C. § 360e(d)(2), which require products to be safe and effective.

15. These manufacturing defects are described in further detail below.

16. Subsequent to implantation, Ms. Laux began experiencing pain throughout her body, including but not limited to pain on the right side of her body near her liver, respiratory congestion/difficulty breathing, a cracking sound on the right side of the neck, vision and eye issues, severe vertigo lasting for weeks at a time, tinnitus, pain, and severe fatigue, including shooting pain in the forearms and hands, and tingling and numbness in her arms, hands, and other parts of her body, among other serious issues, which required many emergency room and urgent care visits.

17. Ms. Laux did not learn, and did not have reason to learn, of any correlation between the implants and these health issues at the time.

18. On May 21, 2014, Ms. Laux underwent a visual contrast sensitivity test, which test revealed results consistent with bio-toxins from mold inside her breast implants.

19. On May 22, 2014, an ultrasound examination confirmed debris floating inside of both breast implants.

20. On May 23, 2014, the implants were explanted by Susan Kolb, M.D., who determined that they were leaking bilaterally. The surgery lasted over seven hours.

21. Dr. Kolb then treated Ms. Laux with anti-fungal medications, as well as a regimen(s) of bio-toxin detoxification, and other treatments.

22. Ms. Laux's condition has improved since said treatment; she continues, however, to experience significant lingering effects of the defectively manufactured implants.

23. In or around June 2015, Pierre Blais, Ph.D., an expert in the field, examined Ms. Laux's actual implants and performed a failure analysis.

24. A true and correct copy of Dr. Blais' report of his failure analysis is attached to this Complaint as **Exhibit "A."**

25. Among many other things, with regard to the specific implants Ms. Laux received, Dr. Blais opined as follows:

a. "Errors occurred in the formulation of the shells and the way in which they were cured, making the elastomer vulnerable to the biological environment";

b. "Mechanical defects were obvious on cursory inspection";

c. There was an "ill-fitting valve cap on both implants, which self-expelled from the valve orifice";

d. "A competent quality assurance protocol would have noted the defects and rejected the implants";

e. "Explanted mammary implants with deviant fabrication characteristics are found in significant quantities, raising concerns about manufacturing and prevailing quality assurance practices";

f. "Ms. Laux's saline implants incorporate an historically unreliable filling valve";

g. "Both of Ms. Laux's implants embody all of the above noted problems and most probably leaked from the outset";

h. "The examination also revealed multiple fabrication errors including deformed parts, an oversize valve orifice and undersize valve cap";

i. "[N]either of the valves on Ms. Laux's implants had the capacity to securely retain the fluid within the shell and had no ability to protect the valve mechanism from capsular tissue invasion"; and

j. "In retrospect, and from examination of many such valves made during the last two decades, it appears that caps and valves are made according to lax standards and many caps are mismatched to an oversize valve orifice, as is the case for both of Ms. Laux's implants. … Tissue invasion of the valve mechanism is a sequela of faulty or deformed valve components, as demonstrated for both of Ms. Laux's implants."

26. Dr. Blais further stated that his "examination revealed grossly faulty valves on both implants, an observation consistent with the explanting surgeon's description of implants 'leaking bilaterally,'" and further concluded that "[t]he valve dysfunction *reflected manufacturing defects including incorrectly-molded and deformed parts*. In effect, the valves offered an open pathway for bidirectional fluid flow." (Emphasis added.)

27. He concluded as follows: "In summary, Ms. Laux was implanted with high risk saline inflatable mammary prostheses with a history of morbidity. The implant complications she suffered were a direct consequence of incorrectly-fabricated prostheses. Neither implant could reliably contain fluid and proteinaceous material as well as opportunistic micro-organisms could readily enter the filling fluid. The ability of each implant to accumulate fluid originating from Ms. Laux's body fluids made the implants ideal for maintenance and exacerbation of systemic infective processes. Time will be required to heal the vacated implant sites and the damaged breast structures and for ongoing infective and immunologically-mediated processes to abate."

28. The foregoing defects, and the others stated within Dr. Blais' report, constitute manufacturing defects within the subject Mentor Saline Breast Implants.

29. Said implants were manufactured defectively by Mentor Corporation, Mentor Worldwide, LLC, and/or John Does #1-10.

30. Said implants caused Ms. Laux to suffer from severe and and life-threatening injuries, including debilitating bio-toxin disease, auto-immune disorders, respiratory, neurological, and immune diseases, fibromyalgia, fibrotic masses and fibrils (the start of silicosis, as silica from breast implants was flaking into the wall of the Plaintiff's chest), pain in the forearms and hands, pain on the right side of the body near her liver, difficulty breathing, pain in the middle of the chest, a cracking sound on the right side of the neck, vision and eye issues, severe vertigo, tinnitus, pain, severe fatigue, and disfigurement, among other issues.

31. As a result of the Defendants' conduct, generally and as aforesaid, Ms. Laux has suffered severe and significant physical and emotional injuries and damages, was forced to incur the cost of additional care and treatment, and will incur additional medical expenses and treatment indefinitely into the future, and has sustained economic damages (including but not limited to lost wages), and other severe and significant injuries and damages.

COUNT ONE – PRODUCTS LIABILITY (MANUFACTURING DEFECT)

32. The Plaintiff repeats and realleges the foregoing as if fully stated herein.

33. Defendants Mentor Worldwide, LLC, Mentor Corporation, and/or John Does #1-10 manufactured, distributed, and sold the subject Mentor Saline Breast Implants.

34. Additionally, and/or in the alternative, Defendants Mentor Worldwide, LLC, Ethicon, Inc., Johnson & Johnson, and John Does #1-10 are responsible for said manufacturing, distribution, and sale directly or on a theory of successor liability, and otherwise, as Mentor Worldwide, LLC, Ethicon, Inc., Johnson & Johnson, and/or John Does #1-10 succeeded to the assets, liabilities, and obligations of Mentor Corporation, including but not limited to the obligation to answer in damages for the conduct alleged herein.

35. The Mentor Saline Breast Implants contained manufacturing defects when they left the Defendants' possession, to wit:

a. "Errors occurred in the formulation of the shells and the way in which they were cured, making the elastomer vulnerable to the biological environment";

b. "Mechanical defects were obvious on cursory inspection";

c. There was an "ill-fitting valve cap on both implants, which self-expelled from the valve orifice";

d. "A competent quality assurance protocol would have noted the defects and rejected the implants";

e. "Explanted mammary implants with deviant fabrication characteristics are found in significant quantities, raising concerns about manufacturing and prevailing quality assurance practices";

f. "Ms. Laux's saline implants incorporate an historically unreliable filling valve";

g. "Both of Ms. Laux's implants embody all of the above noted problems and most probably leaked from the outset";

h. "The examination also revealed multiple fabrication errors including deformed parts, an oversize valve orifice and undersize valve cap";

i. "[N]either of the valves on Ms. Laux's implants had the capacity to securely retain the fluid within the shell and had no ability to protect the valve mechanism from capsular tissue invasion";

j. "In retrospect, and from examination of many such valves made during the last two decades, it appears that caps and valves are made according to lax standards and many caps are mismatched to an oversize valve orifice, as is the case for both of Ms. Laux's implants. … Tissue invasion of the valve mechanism is a sequela of faulty or deformed valve components, as demonstrated for both of Ms. Laux's implants";

k. The shells, valves, and valve orifices and caps, among other components, were not manufactured according to Mentor's own design and specifications;

l. The shells, valves, and valve orifices and caps, among other components, were not manufactured in accordance with the FDA's Quality System Regulations and Current Good Manufacturing Practices, 21 C.F.R. § 820.1, *et seq.*, which among other things "require each manufacturer to put in place processes to test products for compliance with product specifications, to check and document compliance with product specifications before products are accepted for sale and use, and to identify and control nonconforming products," thereby rendering the device "adulterated." *See, e.g., Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010) (citing 21 C.F.R. §§ § 820.1(c), 820.72-820.90);

m. The shells, valves, and valve orifices and caps, among other components, were not manufactured in accordance with 21 U.S.C. § 360e(d)(2), which require products to be safe and effective;

n. The Mentor Saline Breast Implants suffered from manufacturing defects, as described in detail above, and in the attached failure analysis; and

o. The Mentor Saline Breast Implants suffered from such other manufacturing defects as will be learned in discovery.

36. Said defects violated the Defendants' duties and obligations set forth in various sections of the *Restatement (Second) of Torts*, including but not limited to § 402A thereof.

37. As a result of the foregoing, the Plaintiff was harmed, and suffered from (without limitation) severe and life-threatening injuries, including debilitating bio-toxin disease, auto-immune disorders, respiratory, neurological, and immune diseases, fibromyalgia, fibrotic masses and fibrils (the start of silicosis, as silica from breast implants was flaking into the wall of the Plaintiff's chest), pain in the forearms and hands, pain on the right side of the body near her liver, difficulty breathing, pain in the middle of the chest, a

cracking sound on the right side of the neck, vision and eye issues, severe vertigo, tinnitus, pain, severe fatigue, and disfigurement, among other issues, all caused by the defectively manufactured implants, which issues persist in whole or in part.

38. The defects within the Mentor Saline Breast Implants caused, or were a substantial factor in causing, the harm to the Plaintiff.

39. The Defendants' conduct in defectively manufacturing said implants was grossly negligent, reckless, and/or willful and wanton, justifying the imposition of punitive damages.

40. As a direct and proximate result of the carelessness, negligence, gross negligence, recklessness, and willful and wanton conduct on the part of the Defendants, by and through their separate and respective agents, servants, workmen, employees, representatives, physicians, nurses, staff, contractors, medical personnel, and employees, and predecessors in interest, the Plaintiff was caused to sustain serious and excruciating permanent physical injuries and agonizing pain, discomfort, mental anguish, loss of enjoyment of life, loss of life's pleasures, and dignitary harm.

41. As a result of her injuries, the Plaintiff has been prevented from performing all of her usual duties, occupations, employment, recreational activities, and avocations, all to her loss and detriment.

WHEREFORE, Plaintiff Anita Laux demands a judgment against Defendants Mentor Worldwide, LLC, Mentor Corporation, Ethicon, Inc., Johnson & Johnson, and John Does #1-10, jointly and severally, for compensatory damages in a sum exceeding $1,000,000, punitive damages, pre- and post-judgment interest, damages for delay, punitive damages, attorney's fees (but only if available by rule or statute), costs of suit, and such other and further relief as this Court deems to be just and proper.

COUNT TWO – NEGLIGENCE

42. The Plaintiff repeats and realleges the foregoing as if fully stated herein.

43. The Defendants manufactured, distributed, and sold the subject Mentor Saline Breast Implants, and had a duty of reasonable care towards the Plaintiff, and/or are responsible for said manufacturing, distribution, and sale on a theory of successor liability.

44. Specifically, Defendants Mentor Worldwide, LLC, Mentor Corporation, and/or John Does #1-10 manufactured, distributed, and sold the subject Mentor Saline Breast Implants.

45. Additionally, and/or in the alternative, Defendants Mentor Worldwide, LLC, Ethicon, Inc., Johnson & Johnson, and John Does #1-10 are responsible for said manufacturing, distribution, and sale directly or on a theory of successor liability, and otherwise, as Mentor Worldwide, LLC, Ethicon, Inc., Johnson & Johnson, and/or John Does #1-10 succeeded to the assets, liabilities, and obligations of Mentor Corporation, including but not limited to the obligation to answer in damages for the conduct alleged herein.

46. The Defendants breached their duty of reasonable care because the Mentor Saline Breast Implants contained manufacturing defects when they left the Defendants' possession, to wit:

a. "Errors occurred in the formulation of the shells and the way in which they were cured, making the elastomer vulnerable to the biological environment";

b. "Mechanical defects were obvious on cursory inspection";

c. There was an "ill-fitting valve cap on both implants, which self-expelled from the valve orifice";

d. "A competent quality assurance protocol would have noted the defects and rejected the implants";

e. "Explanted mammary implants with deviant fabrication characteristics are found in significant quantities, raising concerns about manufacturing and prevailing quality assurance practices";

f. "Ms. Laux's saline implants incorporate an historically unreliable filling valve";

g. "Both of Ms. Laux's implants embody all of the above noted problems and most probably leaked from the outset";

h. "The examination also revealed multiple fabrication errors including deformed parts, an oversize valve orifice and undersize valve cap";

i. "[N]either of the valves on Ms. Laux's implants had the capacity to securely retain the fluid within the shell and had no ability to protect the valve mechanism from capsular tissue invasion";

j. "In retrospect, and from examination of many such valves made during the last two decades, it appears that caps and valves are made according to lax standards and many caps are mismatched to an oversize valve orifice, as is the case for both of Ms. Laux's implants. … Tissue invasion of the valve mechanism is a sequela of faulty or deformed valve components, as demonstrated for both of Ms. Laux's implants";

k. The shells, valves, and valve orifices and caps, among other components, were not manufactured according to Mentor's own design and specifications;

l. The shells, valves, and valve orifices and caps, among other components, were not manufactured in accordance with the FDA's Quality System Regulations and Current Good Manufacturing Practices, 21 C.F.R. § 820.1, *et seq.*, which among other things "require each manufacturer to put in place processes to test products for compliance with product specifications, to check and document compliance with product specifications before products are accepted for sale and use, and to identify and control nonconforming products," thereby rendering the device "adulterated." *See, e.g., Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010) (citing 21 C.F.R. §§ § 820.1(c), 820.72-820.90);

m. The shells, valves, and valve orifices and caps, among other components, were not manufactured in accordance with 21 U.S.C. § 360e(d)(2), which require products to be safe and effective; and

n. The implants were otherwise defectively manufactured, as described above, and in the attached, and as will be learned in discovery.

47. As a result of the foregoing, the Plaintiff was harmed, and suffered from (without limitation) severe and life-threatening injuries, including debilitating bio-toxin disease, auto-immune disorders, respiratory, neurological, and immune diseases, fibromyalgia, fibrotic masses and fibrils (the start of silicosis, as silica from breast implants was flaking into the wall of the Plaintiff's chest), pain in the forearms and hands, pain on the right side of the body near her liver, difficulty breathing, pain in the middle of the chest, a cracking sound on the right side of the neck, vision and eye issues, severe vertigo, tinnitus, pain, severe fatigue, and disfigurement, among other issues. all caused by the defectively manufactured implants, which issues persist in whole or in part.

48. The defects within the Mentor Saline Breast Implants caused, or were a substantial factor in causing, the harm to the Plaintiff.

49. The Defendants' conduct in defectively manufacturing said implants was grossly negligent, reckless, and/or willful and wanton, justifying the imposition of punitive damages.

50. As a direct and proximate result of the carelessness, negligence, gross negligence, recklessness, and willful and wanton conduct on the part of the Defendants, by and through its separate and respective agents, servants, workmen, employees, representatives, physicians, nurses, staff, contractors, medical personnel, employees, and predecessors in interest, the Plaintiff was caused to sustain serious and excruciating permanent physical injuries and agonizing pain, discomfort, mental anguish, loss of enjoyment of life, loss of life's pleasures, and dignitary harm.

51. As a result of her injuries, the Plaintiff has been prevented from performing all of her usual duties, occupations, employment, recreational activities, and avocations, all to her loss and detriment.

WHEREFORE, Plaintiff Anita Laux demands a judgment against Defendants Mentor Worldwide, LLC, Mentor Corporation, Ethicon, Inc., Johnson & Johnson, and John Does #1-10, jointly and severally, for compensatory damages in a sum exceeding $1,000,000, punitive damages, pre- and post-judgment interest, damages for delay, punitive damages, attorney's fees (but only if available by rule or statute), costs of suit, and such other and further relief as this Court deems to be just and proper.

COUNT THREE – BREACH OF WARRANTY

52. The Plaintiff repeats and realleges the foregoing as if fully stated herein.

53. The Mentor Saline Breast Implants contained an express warranty against defects for a period of at least ten years, and an implied warranty of merchantability, and fitness for a particular purpose.

54. Defendant Mentor Corporation breached said warranty in the manner described above.

55. Defendants Mentor Worldwide, LLC, Ethicon, Inc., Johnson & Johnson, and John Does #1-10 are responsible for said breach directly or on a theory of successor liability, and otherwise, as Mentor Worldwide, LLC, Ethicon, Inc., Johnson & Johnson, and/or John Does #1-10 succeeded to the assets, liabilities, and obligations of Mentor Corporation, including but not limited to the obligation to answer in damages for the conduct alleged herein.

56. As a result of the foregoing, the Plaintiff was harmed, and suffered from (without limitation) severe and debilitating bio-toxin disease, auto-immune disorders, respiratory, neurological, and immune diseases, fibromyalgia, fibrotic masses and fibrils (the start of silicosis, as silica from breast implants was flaking into the wall of the Plaintiff's chest), pain in the forearms and hands, pain on the right side of the body near her liver,

difficulty breathing, pain in the middle of the chest, a cracking sound on the right side of the neck, vision and eye issues, severe vertigo, tinnitus, pain, severe fatigue, and disfigurement, among other issues. all caused by the defectively manufactured implants, which issues persist in whole or in part.

WHEREFORE, Plaintiff Anita Laux demands a judgment against Defendants Mentor Worldwide, LLC, Mentor Corporation, Ethicon, Inc., Johnson & Johnson, and John Does #1-10, jointly and severally, for compensatory damages in a sum exceeding $1,000,000, pre- and post-judgment interest, damages for delay, punitive damages, attorney's fees (but only if available by rule or statute), costs of suit, and such other and further relief as this Court deems to be just and proper.

Dated: December 21, 2015

Respectfully submitted,

Robert A. Zeman, Esquire (State Bar No. 149095)
LAW OFFICES OF ROBERT A. ZEMAN
5142 Hollister Avenue, No. 195
Santa Barbara, CA 93111

Alan C. Milstein (*Pro Hac Vice* Forthcoming)
SHERMAN, SILVERSTEIN, KOHL,
ROSE & PODOLSKY, P.A.
308 Harper Drive, Suite 200
Moorestown, NJ 08057

Attorneys for Plaintiff
ANITA LAUX

JURY TRIAL DEMAND

Plaintiff Anita Laux demands a trial by jury as to all counts and causes of action.

Dated: December 21, 2015

Respectfully submitted,

Robert A. Zeman, Esquire (State Bar No. 149095)
LAW OFFICES OF ROBERT A. ZEMAN
5142 Hollister Avenue, No. 195
Santa Barbara, CA 93111

Alan C. Milstein (*Pro Hac Vice* Forthcoming)
SHERMAN, SILVERSTEIN, KOHL,
ROSE & PODOLSKY, P.A.
308 Harper Drive, Suite 200
Moorestown, NJ 08057

Attorneys for Plaintiff
ANITA LAUX